CLEARING THE SMOKE

Assessing the Science Base for Tobacco Harm Reduction

A report by a Committee of the Institute of Medicine

Kathleen Stratton
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Assessing the Science Base for Tobacco Harm Reduction

Definition of Harm Reduction

For the purposes of this report, a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco-related toxicants.

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Potential Reduced-Exposure Products

PREP refers to any product (tobacco-related or pharmaceutical) used for tobacco harm reduction potential.

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Potential Reduced-Exposure Products

Reduced exposure does not assure reduced risk to the individual or reduced harm to the population. Presently we can document the first, possibly predict the second, and only hope for the third.

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Principal Conclusions

Conclusion 1: For many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible.

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Principal Conclusions

Conclusion 2: PREPs have not yet been evaluated comprehensively enough (including for a sufficient time) to provide a scientific basis for concluding that they are associated with a reduced risk of disease compared to conventional tobacco use.

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Principal Conclusions

Conclusion 3: Surrogate biological markers associated with tobacco-related diseases could be used to offer guidance as to whether or not PREPs are likely to be risk-reducing.

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Principal Conclusions

Conclusion 4: Currently available PREPs have been or could be demonstrated to reduce exposure to some of the toxicants in most conventional tobacco products.

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Principal Conclusions

Conclusion 5: Regulation of all tobacco products, including conventional ones and all PREPs, is a necessary precondition for assuring a scientific basis for judging the effects of PREPs and for assuring that the health of the public is protected.

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Principal Conclusions

Conclusion 6: The public health impact of PREPs is unknown. They are potentially beneficial, but the net impact on population health could, in fact, be negative.

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11 Regulatory Principles

All tobacco products (6):

analytic ingredient disclosure, yield assessment, disclose composition and certify no increased risk, toxicity review, performance standards, agency has necessary enforcement powers

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11 Regulatory Principles

Tobacco-related PREPs with claims (4):

toxicology testing to support claims; exposure and/or risk reduction claims allowed; labeling, advertising, marketing are not ‘false or misleading’ with burden of proof on mfg; post-marketing studies including behavior and disease outcomes required

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11 Regulatory Principles

Pharmaceutical PREPs specifically (1):

remain under jurisdiction of FDA,

exposure reduction claims should be allowed if supported by data

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Regulatory Principles

Principle 2: All tobacco products should be assessed for yields of nicotine and other tobacco toxicants according to a method that reflects actual circumstances of human consumption;

when necessary to support claims, human exposure to various tobacco smoke constituents should be assessed using appropriate biomarkers.

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Principle 2 (continued): Accurate information regarding yield range and human exposure should be communicated to consumers in terms that are understandable and not misleading.

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Regulatory Principles

Principle 4: Manufacturers should be permitted to market tobacco-related products with exposure-reduction or risk-reduction claims only after prior agency approval based on scientific evidence (a) that the product substantially reduces exposure to one or more tobacco toxicants

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Regulatory Principles

Principle 4 (continued):
(b) if a risk reduction claim is made, that the product can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects, as compared with whatever benchmark product the agency requires to be stated in the labeling.

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Regulatory Principles

Principle 5: The labeling, advertising, and promotion of all tobacco-related products with exposure-reduction or risk-reduction claims must be carefully regulated under a “not false or misleading” standard with the burden or proof on the manufacturer, not the government. The agency should have the authority and resources to conduct its own surveys of consumer perceptions relating to these claims.

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Regulatory Principles

Principle 6: The regulatory agency should be empowered to require manufacturers of all products marketed with claims of reduced risk of tobacco-related disease to conduct post-marketing surveillance and epidemiological studies as necessary to determine the short-term **behavioral** and long-term consequences of using their products and to permit continuing review of the accuracy of their claims.

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Regulation can help assure:

that appropriate and verifiable science is conducted;

that reduced exposure products will be developed (and marketed);

that reduced-risk and reduced-exposure claims are accurate.

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Regulation is probably less effective (necessary but not sufficient) in assuring that population harm is reduced.

Regulatory Principles 5 and 6 allow for timely consumer perception surveys and for behavioral studies.

These data, combined with a classic but much strengthened public health surveillance system, can at least describe in a timely manner the effects of these products on the health of the nation and allow for corrective action.

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Elements of a Surveillance System

1. Consumption of tobacco products and PREPs

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Elements of a Surveillance System

2. Specific tobacco constituents of both the products and the smoke they generate

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Elements of a Surveillance System

3. Tobacco product marketing, including PREPs

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Elements of a Surveillance System

4. Biomarkers of exposure to tobacco products

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Elements of a Surveillance System

5. Personal tobacco product use and related behavioral patterns

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Elements of a Surveillance System

6. Disease outcomes

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Harm reduction from tobacco is dependent upon the use of the public health tools of regulation, research, surveillance, and education.

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Regulation

- Allows you to document exposure reduction
- gives confidence in and independent verification of predictions of risk reduction
- assures the accuracy of the data and claims

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Surveillance and Research

- give confidence in predictions of harm reduction
- inform regulatory action if harm appears to be increasing, allowing for corrective action

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Education

Perhaps the most difficult of all!

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What would prohibit claims for PREPs today?

Have these claims met the IOM's framework for a public health response to tobacco harm reduction?

Regulatory Principle #4 does allow for "exposure claims….."

BUT: the 'substantial reduction' in exposure should be sufficiently large that independent scientific experts would anticipate finding a measurable reduction in morbidity and/or mortality in subsequent clinical or epidemiological studies

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What would prohibit claims for PREPs today?

Have there been surveys of consumer perceptions relating to the claims (#5)?

Or post-marketing surveillance including behavioral consequences of the products (#6)

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What would prohibit claims for PREPs today?

Has there been toxicology testing (verifiable) to support claims (#8, #3);

Has the labeling, advertising, marketing been shown not to be ‘false or misleading’ with burden of proof on mfg (#5)?

Are post-marketing studies - including behavior and disease outcomes - underway (#6)?

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In addition to issue of claims (all products):

Has there been analytic ingredient disclosure (#1)?

Yield assessment by valid means (#2)?

Toxicity review (#8)?

Performance standards (#9)?

Necessary agency enforcement powers (#10)?

Have pharmaceutical PREP's been given exposure claims (11)?

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What's wrong with the current system regarding PREPs

Does the U.S. have tobacco regulation?

Does the U.S. have a comprehensive tobacco control program?